



September 2, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1613-P
P.O. Box 8013
Baltimore, MD 21244-1850

*Avera Health (IA, MN, NE,
ND, SD)*

*Carolinas HealthCare System
(NC, SC)*

*Community Hospital
Anderson (IN)*

Erlanger Medical Center (TN)

*Fletcher Allen Health
Care (VT)*

Forrest General (MS)

*Franciscan Missionaries of
Our Lady Health System (LA)*

Harris Health System (TX)

Hartford Hospital (CT)

*Ohio Valley Health Services
and Education Corporation
(OH, WV)*

*Raritan Bay Medical Center
(NJ)*

*Robert Wood Johnson
University Hospital (NJ)*

*University of Pittsburgh
Medical Center (PA)*

Re: CMS-1613-P, Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; (Vol. 79, No.134), July 14, 2014.

Dear Ms. Tavenner,

We appreciate the opportunity to provide comments in response to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, which was published in the Federal Register on July 14, 2014.

The Provider Roundtable (PRT) members are from 13 different health systems serving 18 states. PRT members are full-time employees of hospitals. As such, we have a financial interest in fair and proper payment for services provided under the OPPTS.

The members collaborated to provide substantive comments with an operational focus that we hope CMS staff will consider during the annual OPPTS policymaking process. We appreciate the opportunity to provide our comments to the agency. A full list of the current PRT members is provided in Attachment A.

Please feel free to contact me at 225-765-8847 or via email at: Jen21306@ololrhc.com.

Sincerely,

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PRT Chair and
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Comprehensive APCs

Comprehensive APCs (CAPC)

The PRT commends CMS for delaying the initiation of Comprehensive APCs (CAPC) for one year in order to work on a complexity adjustment; we request CMS to delay the initiation for an additional year, based on the significant concerns we note below. While we are not able to present solutions at this time, we know that the CAPC implementation will have a significant impact on providers and hospitals need time to evaluate the impact prior to implementation.

Ablations were added to the CAPC methodology as a migration from a comprehensive APC. The PRT is concerned by this, since the new combination codes have not been reported for very long, and so were not included in the modeling for the CPAC logic. They are also not device-dependent APCs so they do not meet that criteria to become a current CPAC.

Some procedures assigned status indicator J1 are *not* always the primary procedure on a claim. Depending on the circumstances, these can actually be adjunctive/supportive to another service. We present two examples below:

1. The codes representing the insertion of a tunneled central venous catheter (e.g., CPT codes 36561 and 36558) can be the primary service if that is the only procedure performed. When this same procedure is performed for the purpose of chemotherapy administration or other drug administration services, however, the insertion becomes *supportive* of the chemotherapy/drug administration services. (The purpose of the catheter insertion is to establish vascular access to a large volume blood vessel for administering the chemotherapy/drug(s).)
2. The insertion of a pleural catheter represents the same scenario. This insertion may be for the sole purpose of administering chemotherapy to the pleural space, or a drug for the purpose of sclerosing the pleural space in the incidence of a recurring effusion. Again, the purpose is supportive for the administration of the drug.

Many providers report chemotherapy services on a series/recurring claim. While this service is not mandated to be reported as a recurring claim by the Claims Processing Manual, providers have that option for reporting these services. Multi-day claims are included in the CAPC methodology. The PRT supports the CAPCs, but we are concerned about instances when the highlighted codes indicated below are billed on a series claim for chemotherapy. These services are by nature supportive to oncology treatment.

In the spirit of expanding packaging, the PRT recommends that CMS create specific packaging logic that packages the catheter insertion procedure into the chemotherapy administration procedure provided on the same date of service.

The CAPCs and specific codes assigned to the CAPCs are listed below:

652	Insertion of Intraperitoneal and Pleural Catheters	32550	Insert pleural cath
		49418	Insert tun ip cath perc
		49421	Ins tun ip cath for dial opn

427	Level II Tube or Catheter Changes or Repositioning	47525	Change bile duct catheter
		47530	Revise/reinsert bile tube
		49423	Exchange drainage catheter
		49436	Embedded ip cath exit-site
		50387	Change ext/int ureter stent
		50398	Change kidney tube
		50688	Change of ureter tube/stent
		62225	Replace/irrigate catheter

622	Level II Vascular Access Procedures	36260	Insertion of infusion pump
		36557	Insert tunneled cv cath
		36558	Insert tunneled cv cath
		36560	Insert tunneled cv cath
		36561	Insert tunneled cv cath
		36563	Insert tunneled cv cath
		36565	Insert tunneled cv cath
		36566	Insert tunneled cv cath
		36570	Insert picvad cath
		36571	Insert picvad cath
		36578	Replace tunneled cv cath
		36581	Replace tunneled cv cath
		36582	Replace tunneled cv cath
		36583	Replace tunneled cv cath
		36585	Replace picvad cath
		49419	Insert tun ip cath w/port

* For CAPC 0622, the codes listed are related to chemotherapy services and do not reflect all codes assigned to the CAPC.

The PRT requests that CMS *exclude* the codes highlighted in the tables above from the CAPC methodology; they are not always the primary procedure and often are actually supportive to other primary procedures.

Under the current proposal, the J1 methodology is applied at the claim level. If a provider chooses to report chemotherapy services on a series claim, and the beneficiary has a central venous catheter/system inserted for the provision of the chemotherapy, all dates of service and items on the claim will package into the central venous catheter procedure because it is assigned to status indicator J1. In this situation, it does not make sense for all services to package into the catheter insertion procedure, since that is actually the supportive procedure.

We contrast this with another frequent example: pacemaker insertion. The insertion of a pacemaker is the primary service being provided to the patient, so it does make sense for everything to package into this procedure as the primary service.

The PRT acknowledges that the series claim is a provider decision for these services, but note that providers have operational and beneficiary reasons for making this choice. For providers that utilize series/recurring claims, the assignment of the codes across a 30-day period (or anything other than a single encounter claim) noted above to status indicator J1 presents some consequences which we believe CMS did not intend.

If CMS progresses with these CPACs, it will create a huge operational burden for providers to generate a daily claim for the services. Many facilities report these services on a 30-day basis, and many facilities have made the choice to bill individual claims per date of service. We believe that CMS *must* provide additional information regarding its intent; what has been a provider choice will now become a financial decision. While no additional funds will be available, CMS is likely to see a huge increase in the number of claims it receives, because the series claim will no longer make fiscal sense to hospitals that currently bill monthly.

The other impact will be on the beneficiary, since registration processes, MSP paperwork, and consent to bill paperwork must be completed every day. The beneficiary will receive an increased number of bills/statements, since billing will be performed on a per date of service basis. CMS should give a transparent example regarding payment changes and their impact in order to assist providers in understanding the effect of continuing to use series billing. The PRT is not requesting that CMS mandate any particular action on a provider's part, but that it provide a better sense of the impact in order to aid provider education.

In addition, we do not believe that providers should have to assume the operational burden to change series billing (for the reasons noted above). Instead, we believe that CMS should program the claims processing methodology to limit the scope of dates that are included in the Comprehensive APC. It seems that CMS recognizes that repetitive services could be billed on a multi-day claim, and we appreciate that CMS gave the flexibility in the manual.

In order to maintain this flexibility, the PRT recommends that CMS create the methodology on its side to have the Comprehensive APC cover and include the date of service of the J1 plus one day. If observation is one of the services provided, then the CAPC methodology should include those charges and we believe this can be done by creating packaging logic so that the presence of G0378 and/or revenue code 0762 is packaged into the CAPC.

This is a new concept and, while it feels right to us, the PRT did not have time to model the concept to assess whether it was the best methodology. In the spirit of getting to a more accurate bundle, the PRT recommends that CMS limit the span to the date of the J1 service plus one day after the service is rendered. If the Agency proceeds with the 30-day

claim methodology, providers will require at least a six-month delay in order to change operational processes related to billing all non-mandated recurring services on separate claims.

We appreciate the refinements that CMS made to the complexity adjustment criteria. While the complexity adjustment is a reasonable mechanism to account for substantial costs within an episode, the PRT is concerned about certain encounters where the complexity adjustment will result in a Comprehensive APC payment that will not reasonably pay for the spectrum of services provided in the encounter. We realize that CMS has accounted for significant second primary procedures *or* a significant add-on code as a trigger for the complexity logic; we note that there are, however, situations that warrant making an *additional* adjustment when both multiple primary and multiple add-on codes occur in the same encounter.

For instance, it is quite common for interventions to occur in multiple major coronary arteries and individual branches. We reviewed many specific claims to assess the impact of the proposed Comprehensive APC changes and wish to share the following common example where we have significant concerns (we have omitted the packaged stents and supplies):

- C9600 – LD (Perc drug-el cor stent sing; Left anterior descending)
- C9601 – LD (Perc drug-el cor stent ea addl branch; Left anterior descending)
- C9600 – RC (Perc drug-el cor stent sing; Right coronary)
- C9601 – RC (Perc drug-el cor stent ea addl branch; Right coronary)
- 93458 (Left heart artery/ventricle angio)

HCPCS	Modifier	Short Description	Units	2014 SI	2014 APC	2014 Pmt	2015 SI	2015 APC	2015 Pmt
C9600	LD	Perc drug-el cor stent sing	1	T	656	\$7,714.02	J1	319	\$14,759.02
C9600	RC	Perc drug-el cor stent sing	1	T	656	\$3,857.01	J1*		0
93458		L hrt artery/ventricle angio	1	T	80	\$1,293.49	T*		0
C9601	LD	Perc drug-el cor stent bran	1	T	656	\$3,857.01	N		0
C9601	RC	Perc drug-el cor stent bran	1	T	656	\$3,857.01	N		0
Total APC Payments						\$20,578.54			\$14,759.02

The PRT requests that CMS add additional logic and an additional APC (Level IV Endovascular Procedures) to drive complex cases with multiple major coronary artery interventions combined with multiple additional branches (and the significantly increased associated supply/implant costs) to a more appropriate comprehensive payment.

Exclusion of Preventative Services

The PRT supports CMS’ decision to exclude preventative services from its packaging proposals (both ancillary packaging and comprehensive APCs). We believe such packaging could ultimately reduce beneficiary access to these vital services. In the same vein, we encourage CMS to clarify, in its rule-making, that preventative laboratory

services are *also* excluded from the laboratory packaging initiative, which was finalized in the 2014 OPPS Final Rule.

Device-Dependent Edits

CMS proposes to continue to require the reporting of a device code for all procedures assigned to a device-dependent APC for CY 2015. In order to reduce administrative burden, CMS proposes that the device edits be satisfied by the presence of any medical device C-code that is currently included in the device edits, rather than requiring specific device C-code(s). CMS originally implemented these edits in response to commenters' concerns that devices and other products were not being reported consistently, especially those associated with device-dependent APCs. The PRT supported CMS' introduction of these edits to ensure correct data for future rate-setting and to reflect all resources expended for the care of beneficiaries.

The PRT respectfully disagrees with CMS' assertion that these edits are burdensome to hospitals and are no longer required; in fact, hospitals are now experienced in coding and claims submission using the edits. These edits, far from being burdensome, have actually *helped* facilities insure that highly expensive devices are billed correctly with their associated procedure(s).

We are deeply concerned by CMS' proposal to allow *any* device code to satisfy an edit. Incomplete and/or incorrect data will severely compromise the cost data used in future rate-setting for Comprehensive APCs. We believe that continuing the specificity of these edits is critical to maintaining the data's integrity — particularly with the initiation of Comprehensive APCs.

To illustrate our concern, we offer an example: CPT code 33206 (insertion of heart pacemaker) can be billed with a single or dual rate-responsive or non-rate responsive pacemaker either with or without transvenous VDD leads. A pacemaker generator costs \$5,000, while a lead costs \$500. If a claim lacks the appropriate device code for the pacemaker and lead, or if the device code reported was for a drainage catheter rather than the pacemaker/lead, the reported cost data will be grossly inaccurate.

The PRT disagrees with CMS's proposal to alter the device-procedure edits to allow *any* of the device codes present on the claim to satisfy the edits and urges CMS to maintain the current device-to-procedure and procedure-to-device edits process.

Blood & Blood Products

CMS notes that when Comprehensive APC payments were established, the costs for blood and blood products were included, calculated based on the usual blood-specific CCR methodology. For this reason, CMS proposes *not* to make separate payments for blood and blood products when they appear on the same claim as services with status indicator J1.

The amount of blood and blood products required in any clinical situation is patient-specific, and no two scenarios are exactly the same. Based on the stated purpose that Comprehensive APCs will provide hospitals with flexibility and choices regarding serving beneficiaries, the PRT submits that this is a scenario where the cost and usage do not fall under the control of hospital providers. There are no substitutes for the blood and blood products in the required situations; when these are needed, they are needed immediately. Hence, the intent of CAPCs related to hospital flexibility and choices does not exist in these specific situations.

The variance in cost can be significant (as has been noted in the rate-setting process for blood and blood products over the years) and providers can neither control nor change it. Blood loss is a complication of a procedure and, under the Inpatient Prospective Payment System (IPPS) reporting structure, creates a CC or MCC for many DRGs. It is not possible to capture that level of acuity in the Outpatient Prospective Payment System (OPPS), since the system has no severity adjustment. In other words, because the blood products and transfusion are to be packaged, there is no mechanism to recognize the cost and complexity adjustment when these services are needed.

The PRT believes it is important for continued, separate reimbursement for blood and blood products to be made while CMS evaluates the comprehensive APC methodology; only by doing so can the agency ensure that all costs are being allocated appropriately.

The PRT requests that CMS further examine data regarding the number of claims that contain blood and blood products and the packaging methodology to insure that all costs are captured. This must be done before the agency includes blood and blood products in the Comprehensive APC reimbursement. We believe that the key line item for this review is CPT 36430 (transfusion of blood/blood products), as it appears once per encounter and there may be multiple blood products transfused to the beneficiary in a single encounter. The PRT requests that CMS provide the results of the data analysis to providers in the Final Rule.

Based on the above, the PRT respectfully disagrees with CMS' proposal to include payment for blood and blood products when they appear on the same claim as services assigned to a Comprehensive APC.

Add-on Codes

Add-on Codes have been packaged services since January 2014 and we acknowledge that the next logical step is to include them in the Comprehensive APCs. The PRT is pleased and appreciative that the presence of these codes on the claim is factored into the complexity adjustment.

Packaging Prosthetic Supplies

The PRT is concerned with CMS' proposal to package all prosthetic supplies, and with how that proposal relates to the statutory prohibition against unbundling (Section 9343(c) of OBRA 1986 and implementing regulations at 42 CFR 411.15(m)).

The basic rule, found at 42 CFR 411.15(m), excludes from coverage — except as provided in paragraph (m)(3) of the section — any service furnished to:

“a hospital outpatient (as defined in §410.2 of this chapter) during an encounter (as defined in §410.2 of this chapter) by an entity other than the hospital unless the hospital has an arrangement (as defined in §409.3 of this chapter) with that entity to furnish that particular service to the hospital's patients.

As used in this paragraph (m)(1), the term “hospital” includes a CAH. The “under arrangement” provision typically means the hospital is financially responsible for the service meaning the hospital bills for the service and provides payment to the separate supplier. Section 2 further states the services subject to exclusion from coverage under the provisions of this paragraph (m) include, but are not limited to, clinical laboratory services; pacemakers and other prostheses and prosthetic devices (other than dental) that replace all or part of an internal body organ (for example, intraocular lenses); artificial limbs, knees, and hips; equipment *and supplies covered under the prosthetic device benefits*; and services incident to a physician service” [emphasis added].

The PRT is concerned about the intersection of the proposed OPSS prosthetic supply policy and the existing prohibition against unbundling. We fear this will force hospitals to arrange and bill, under their provider number, any and all supplies and prosthetics that are delivered at an outpatient hospital visit — even when the supply or prosthetic is provided by a *separate* prosthetic supplier and will be primarily used by the beneficiary at home.

CMS has already recognized an exception to the prohibition against unbundling for the Inpatient Prospective Payment System for prosthetic supplies. In that case, CMS provided an exception whereby the separate prosthetic supplier can bill for a DME/Prosthetic device or supply delivered up to two days prior to discharge. (See Medicare Claims Processing (PUB. 100-04) Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) 110 - General Billing Requirements - for DME, Prosthetics, Orthotic Devices, and Supplies). The PRT requests that CMS provide a similar exception under the OPSS.

Without such an exception under the OPSS, the proposal creates a compliance concern for facilities, which would be in violation of the prohibition against unbundling noted above. Without such a clarification, CMS' claims and cost data will reflect different practices based on different hospitals' interpretations of this policy. Some hospitals may believe they have to bill *all* prosthetic supplies that are ordered and delivered at an outpatient encounter; others may believe that the separate prosthetic company can bill supplies ordered, but not those delivered at an outpatient encounter; still others may always allow the prosthetic supplier to bill any ordered or delivered supplies. Differences

in interpretations will provide issues with future rate setting under the OPSS and, as already noted, create a compliance concern for providers.

Packaging

The PRT understands and generally supports CMS' goal of transitioning the Outpatient Prospective Payment System to one that is less like a fee schedule and more like a prospective payment system. As CMS states, its packaging proposals are intended to address services that are “*integral, ancillary, supportive, dependent, or adjunctive*” to a primary service. The PRT has concerns, however, regarding the financial impact that increased packaging will have on hospitals.

The PRT supports the fundamental concept of larger payment bundles. Nonetheless, we remain concerned about the adequacy of payments to hospitals, given the significant packaging provisions CMS has already finalized, and those proposed for CY 2015. We believe it is inappropriate for CMS to try and “transform” the OPSS in just two rule-making cycles. We urge CMS to move more slowly and provide stakeholders time to assess the true impact of its packaging proposals — which now requires the review of entire claims rather than simply comparing line item/individual service level payments and APC assignments.

We have noted that it is incredibly difficult for stakeholders to separately analyze the general “ancillary packaging” proposal and the Comprehensive APC proposal, due to the overlap that exists between code usage in both scenarios. It is extremely hard to untangle the methodology in these two initiatives. Given that, and with transparency being requested by the provider community regarding provider charges, we are not confident that CMS accurately and fully redistributed those dollars to the remaining APCs. With these caveats in mind, the PRT offers the following comments on CMS' packaging proposal.

Ancillary Services and Q1 Status Indicators

For CY 2015, CMS proposes to conditionally package certain ancillary services with an initial geometric mean cost of less than \$100. If CMS moves forward with this, the PRT favors the use of conditional packaging (i.e., Status Indicator Q1) over other types of packaging.

Conditional packaging better promotes the intent of prospective payment by packaging services when they are integral, ancillary, supportive, dependent or adjunctive to a primary service, while allowing separate payment when the services are provided independently. Providers prefer the use of status indicators over modifiers due to the significant operational burden related to reporting modifiers (as is seen in the application of modifier L1 for lab services.) In addition, this allows for more consistent claims processing across all of our payers.

The PRT notes that the CY 2015 proposal reflects a significant increase in the number of codes with a Q1 status indicator from 12 in CY 2014, to 511 in CY 2015. This significant increase in the use of STV conditional packaging increases the likelihood of claims with multiple Q1 codes without a corresponding S, T, or V code. Currently, when multiple Q1 codes are reported on a claim without a primary service (i.e., an S, T, or V code), payment is made for only the highest-weighted Q1 code.

Given the exponential increase in status indicator Q1 codes, the PRT asks CMS to provide some level of separate payment for each Q1 code on a claim when there is no primary S, T, or V service. We understand that the agency has packaged to the extent that certain procedures/tests/services were combined on claims. Until the level of packaging attributed to each Q1 service is made available to the public, however, we cannot determine whether the new payment rates are appropriate. The PRT recommends that CMS reimburse providers in some manner for each Q1 on a claim when there is no STV service on the claim if CMS finalizes its proposal to package ancillary services in CY 2015.

We understand that, under a prospective payment system, the reimbursement should even out over the entire claims population. Under the new proposal, however, providers lose not only on the STV claims, but also on Q1-only situations. As CMS staff noted at the recent HOP Panel meeting, the payment for these procedures when performed without STV items on the claim should make up for some of the lost reimbursement due to packaging. If only one Q1 line item is reimbursed on an “all Q1” claim, this equalization is not likely to occur, even “on average”.

The examples below help illustrate this point:

Example 1

CPT Code	CPT Code Description	2014 SI	2014 Payment Rate	2015 SI	2015 Payment Rate	Change in Payment
71100	Radiologic examination, ribs 2 views; single view, frontal	X	\$57.35	Q1	\$59.93	
93005	Electrocardiogram, routine ECG with at least 12 leads; tracing only, without interpretation and report	S	\$27.12	Q1	\$77.63	
Total Payment			\$84.47		\$77.63	-\$6.84

Example 2

CPT Code	CPT Code Description	2014 SI	2014 Payment Rate	2015 SI	2015 Payment Rate	Change in Payment
71070	Radiologic examination, pelvis, 1 or 2 views	X	\$57.35	Q1	\$95.36	
73510	Radiologic examination, hip, unilateral; complete, minimum of 2 views	X	\$57.35	Q1	\$59.63	
Total Payment			\$114.70		\$95.36	-\$19.34

Example 3

CPT Code	CPT Code Description	2014 SI	2014 Payment Rate	2015 SI	2015 Payment Rate	Change in Payment
72170	Radiologic examination, chest; single view, frontal	X	\$57.35	Q1	\$95.36	
73510	Radiologic examination, hip, unilateral; complete, minimum of 2 views	X	\$57.35	Q1	\$59.63	
93005	Electrocardiogram, routine ECG with at least 12 leads; tracing only, without interpretation and report	S	\$27.12	Q1	\$77.63	
99284	Emergency department visit	Q3	\$293.71	Q3	\$335.85	
Total Payment			\$435.53		\$335.85	-\$99.68

Packaged Laboratory Services and the L1 Modifier

Because status indicator initiated bundling is less of an operational burden for providers, the PRT asks CMS to create a status indicator for laboratory services that would conditionally package those services when billed with a primary service, but trigger payment from the clinical laboratory fee schedule (status indicator A) when they are not. This would resemble the way CMS proposes to package ancillary services, except the status indicator would trigger payment for all laboratory services when there is no primary service on the claim.

The current modifier application process is very burdensome to providers, as hospitals must set up their internal systems to append the L1 modifier to indicate separately

payable labs (e.g., lab only claims) for outpatient laboratory services (TOB 13X). In many cases, this process requires manual intervention. Further, the PRT's experience shows the modifier application process is implemented differently at its member hospitals due to differing systems and billing processes. This variability is unavoidable across the hospital industry, given the different billing, coding, and information systems in use.

We are deeply concerned that this variability could result in inaccurate and inappropriate payments. We sincerely believe it is in the best interest of both CMS and its provider stakeholders for the agency to eliminate the use of modifier L1; instead it should use conditional packaging logic where separate payment is based on whether other services are present on the claim for the same date of service. We believe CMS can initiate this quickly and easily allowing the agency to meet its objective of packaging while also reducing provider burden. Moreover, CMS' use of conditional packaging will ensure consistent and correct adjudication of claims through the outpatient code editor, as well as ensure appropriate payment. It will also reduce the enormous operational burden the modifier has created for providers.

HCPCS Code G0463

The PRT recommends that CMS package the costs of HCPCS code G0463 (Hospital outpatient clinic visit) when it occurs on the same date of service with one of the following CPT codes:

- 90833, psychotherapy, 30 minutes with patient and/or family member when performed with an evaluation and management service
- 90836, psychotherapy, 60 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)
- 90838, psychotherapy, 60 minutes with patient and/or family member when performed with an evaluation and management service.

These psychotherapy codes are not "add-on codes" in the same sense as other add-on codes. These codes represent psychiatric services provided in addition to E/M services. In the instances when a clinic visit is reported with one of these codes, it is actually the clinic visit that is supportive/adjunctive to the psychotherapy service. Implementing this request will require CMS to create some additional claims processing logic so that the costs of G0463 are packaged *into* the above psychotherapy CPT codes when they are present on the same date of service. We believe that this extra effort will be minimal and will result in more appropriate payment rates.

Line Item Charge Data

CMS states that line item data on claims are not used in the rate-setting process if the charge is lower than the APC payment. CMS does not instruct nor mandate the methodology for providers to set charges; nonetheless, in order for the cost to be included in the claims data, providers must ensure that line item charges are above the APC

payment rate. With increasing layers of packaging, as charges are updated going forward, providers will have to evaluate their methodologies, since many services will be below the payment for the APC due to the packaging. (For example, the EKG line item reimbursement increases to \$97.00 based on packaging under the CY 2015 methodology.) Providers will have to consider their charges based on the new APC payment amount in order to include the information in the future rate-setting process.

We suggest that line item cost analysis should be based on the individual item's mean cost amount, not at the APC payment amount. CMS should no longer disregard the charges that are less than the APC payment because a payment rate is set for each Q1 based on packaging. Providers evaluate charges based on the APC rate due to CMS' logic that line items lower than the APC rate are disregarded during rate setting. But, charges are not always set based on the APC rate, since providers must consider how all payers are processing claims, and not all payers use the APC methodology. Providers will now have to determine how to allocate charge dollars, since everyone must be charged the same, regardless of payer.

The PRT recommends that CMS review and adjust the trim criteria it uses since APC payment rates now include more packaged cost/charges and are no longer based on an individual service cost/charge. With additional packaging, and the requirement for hospitals to continue to submit line item charges when appropriate, the trim criterion is no longer logical. Another consideration with respect to transparency is that beneficiaries may be very confused when they receive the same service on different occasions and one of those occasions is without coinsurance/copay and then, at another encounter coinsurance will be required. The PRT's intent in raising these issues is to alert CMS to the types of questions that will arise and that the agency should address as it moves the OPSS to more of a prospective payment system.

Drug Administration Codes

The PRT appreciates that CMS decided to continue excluding drug administration from the proposed expansion of packaged ancillary services. CMS notes that various alternative payment policies are being examined for drug administration services. As CMS is well aware, the current drug administration codes include "dollars" for packaged drugs for which providers do not receive separate payment. We remind CMS to be cognizant of the history of this drug packaging and proceed carefully with any further packaging recommendations for drug administration services. We further note that continuing separate payment for drug administration is one means by which the OPSS can recognize varying patient acuity during an OPSS encounter.

Skin Substitutes

The PRT recognizes that skin substitutes are packaged unless they are new and have been granted pass-through payment status for a period of time. We disagree with CMS' proposal to change the classification of skin substitutes from biological to device for the purposes of pass-through payment evaluation. CMS has already classified these items

under the drug/biological category and has a standing process for pass-through payment considerations. The PRT has found nothing that would support the change to the medical device category other than the pass-through payment process. The process for medical devices and the criteria that must be met take longer and are starkly different than that for drugs and biologicals.

CMS noted in the Federal Register that biological or synthetic skin replacement material is not a device; the PRT agrees with this statement. The main intent and use of skin substitutes is for the treatment of wounds that have failed other methods. The population is faced with increases in the incidence of decubitus ulcers, diabetes, and significant wounds that significantly affect the person's quality of life and influence readmissions. It should not be more difficult for these items to qualify for pass-through payments, since the next new skin substitute may be a breakthrough item that keeps tissue viable and allows limb salvaging. Hence, the PRT recommends that skin substitutes remain categorized as a biological.

Conclusion

In summary, the PRT recommends and requests that CMS:

1. Create a reimbursement structure that provides some level of reimbursement for each Q1 procedure on a claim (possibly similar to the status indicator T methodology currently in use);
2. Create a status indicator for laboratory services to conditionally package those services when billed with a primary service, but trigger payment from the clinical laboratory fee schedule (status indicator A) when they are not.
3. Package costs for HCPCs code G0463 into the psychotherapy codes when reported on the same claim;
4. Alter the methodology where line items with charges less than APC reimbursement are included in the claims data for rate setting due to the impact of the Comprehensive APC packaging methodology;
5. Adjust the trim criteria currently being utilized for rate setting to account for the initiation of the Comprehensive APC methodology;
6. Do not implement the change in skin substitutes' classification from biological to device for pass-through payment evaluation.

The PRT encourages CMS to continue to assess the financial impact of OPSS packaging on hospitals, and we encourage the agency to work with representative members of the provider community such as the American Hospital Association and the PRT. We believe this collaboration is *crucial* to ensure that all changes to OPSS are effective in promoting the provision of efficient and high-quality health care without unduly burdening providers, beneficiaries, or CMS.

In the spirit of collaboration, the PRT recommends that CMS develop a long-term plan that includes goals and timelines for implementing additional packing. The current process forces providers to analyze claims singularly from the previous to the current year. A more efficient approach would be to develop the long-term goal and determine,

with provider input, how best to achieve that goal. Such a process would resemble the way CMS currently addresses the long-term goals of the Hospital Outpatient Quality Reporting Program.

We further note that the development of such a long-term plan would help stakeholders (including CMS) more accurately project the financial impact of the packaged services than does the current year-to-year approach. A long-term plan would also allow providers the time necessary to model the proposals from both a financial and operational process perspective.

E/M Visits

The PRT understands and supports the premise of packaging and CMS' plan to continue to package related services. The significant packaging of related services which has occurred over the past few years were for services that CMS indicated could be reasonably viewed in the same "family." In general, providers have responded to this packaging in a manner demonstrating support for both CMS and the logic that underlies packaging.

We wish to stress, however, that packaging related services *and* compressing patient acuity visit level codes into a single G HCPCS code has resulted in *significant* and *negative* financial impact for providers.

Prior to January 2014, Medicare received claim-level detail specific to patient acuity level from providers through claims submitted using CPT codes 99201-99215 for facility visits. CMS proposes to continue the current policy adopted in 2014: the assignment of HCPCS code G0463 for *any* HOPD clinic visit. The PRT believes that the patient acuity detail provided by CPT or HCPCS codes assigned for the clinic visit *must* be restored by CMS in order to accurately reflect the unique and specific resources facilities expend to provide care for clinic patients.

In the 2015 OPSS Proposed Rule, CMS describes its intent to continue the current methodology for reporting ED visit levels and continue to "further explore" the issues related to ED visits, including concerns about costly patients, such as trauma patients. The PRT appreciates CMS decision to continue with the current ED level CPT codes, which have been adopted by providers over the years. CMS' own data have established that facilities consistently apply their own internal criteria. While CMS is focused on costly and/or trauma patients, providers know, from our own data, that patient's acuity levels and costs of care span all ED levels.

For this reason, it is imperative that any methodology implemented by CMS in the future must continue to reflect patient acuity levels and separately recognize the unique, costly, and highly technical resources expended for trauma patients in the ED setting. We believe it is critically important to continue to use a patient acuity coding system for all ED visit levels. These are necessary for providers to ensure their claims data accurately

reflect patient acuity. We believe that providers should be reimbursed based on this acuity in order to reflect the true costs of providing care.

The PRT again voices our opposition to the single G-code clinic level (G0463) for the following reasons:

First, the single level G-code does not adequately reflect patient acuity in the clinic setting — nor will it *ever* reflect the acuity and resource differences among patients seen in this setting. We continue to be concerned that certain clinic types are being rewarded, while others are being penalized on a consistent basis. We urge CMS to recognize the negative financial impact that this process has on providers with consistently higher visit levels due to the types of patients they routinely treat.

Implementing this proposal has not only compressed provider reimbursement but also removed CMS' ability to identify variations in cost stemming from patient acuity. Compressing these CPT codes to a single G code has not removed any differentiation in patient acuity in the real world, but has limited the data CMS receives. Claims data for clinic visits now presumes that *all* patients have the same level of services — which is highly inaccurate. We are also concerned that, because clinic visit resources are not reimbursed appropriately with the single G-code, there is the potential for disrupted access to services, and/or fragmentation of care delivery in order for hospitals to be reimbursed for all costs.

Second, one of the most critical points in CMS' 2000 directive (which has been repeated annually) is that the facilities' internal guidelines "*be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.*" The PRT believes this statement clearly indicates CMS' awareness that resources expended by the facility differ significantly between visit levels. We do not know why CMS has implemented a single HCPCS code that prevents Medicare from receiving the unique patient acuity level data that are afforded by use of a multi-level set of codes.

Third, most non-Medicare payers require the use of the five-level CPT code structure. This has resulted in providers having to implement a dual system that uses the single HCPCS G-code for CMS' beneficiaries, and the CPT codes for non-CMS payers. Although CMS has stated that decreasing provider burden was one goal of the single HCPCS G-code requirement, the process has had the opposite effect on provider burden.

The PRT's specific recommendations are as follows:

- 1) The PRT urges CMS to return to a reporting structure that accurately reflects patient acuity, and discontinue the single HCPCS G-code for reporting clinic visits.
- 2) The PRT recommends, again, that CMS work with the American Medical Association (AMA) to develop facility-specific CPT codes for E/M clinic visits (with no distinction between new and established patients), Type A ED visits, and Type B ED visits. This will have several benefits, including to:

- a. Eliminate the long-standing confusion stemming from hospitals having to report physician-applicable nomenclature with hospital-developed guidelines.
 - b. Simplify and ensure consistent reporting of hospital visits for all providers, and capture clinical and resource differences.
 - c. Allow CMS to collect accurate and complete outpatient clinic and ED visit data from hospitals, which is critical to create future APC payment rates.
- 3) The PRT recommends that CMS seek input from industry stakeholders to develop descriptions for these new codes that allow for their consistent application by hospital outpatient clinics/facilities. Hospital representatives must be involved in this effort. The PRT has spent considerable time working on developing guidelines and is very happy to participate in efforts to generate clear language for the code descriptors.

We recognize it will take some time for the new codes we recommend to be developed and implemented. In the interim, if CMS feels that it must shift from the existing use of CPT codes, we recommend migration to five levels of HCPCS G-codes for clinic visits (GVVV1 through GVVV5), to five levels of HCPCS Type A ED visits (GAAA1 through GAAA5), and to maintain the existing Type B HCPCS G-codes, which will allow providers to continue using their existing guidelines. Although providers generally do not support CMS creating G-codes, we believe most would understand — and could accommodate this interim change — if CMS felt it was necessary as it works with the AMA to develop CPT codes for hospital use.

Proposed Changes to the Inpatient List

CMS has proposed that CPT 22222 (*Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic*) be returned to the Inpatient-only List. Until December 31, 2004, 22222 appeared on the Inpatient-only List. Effective for January 1, 2005, the code was changed to Status Indicator (SI) T, payable under the OPSS and has remained off the Inpatient-only List since then.

The PRT supports CMS' proposal to return CPT code 22222 to the Inpatient-only List. When queried, a respected hospital surgeon at a member hospital summed up his thoughts on the procedure by saying, "There are sufficient risks to warrant its being an inpatient only procedure, especially since some of the more common complications (pneumothorax or hemorrhage due to the anterior approach through the chest) can frequently be very occult in the immediate postop period, and then rapidly progress to a life threatening complication."

In addition, the PRT notes that the surrounding CPT codes (22206, 22207, 22208, 22210, 22212, 22214, 22216, 22220, 22224, and 22226) are all on the Inpatient-only List with an SI of C. Thus, only 22222 is payable under OPSS, with an SI of T.

CMS does not propose removing any CPT codes from the Inpatient-only List for CY 2015, but the PRT would like to recommend that 63043 be removed from the list (*Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial*

facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (List separately in addition to code for primary procedure) as well as 63044 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (List separately in addition to code for primary procedure).

CPT 63043 and CPT 63044 are add-on codes to CPT 63040 and CPT 63042, respectively, both of which have a SI T and are payable under OPSS. Other CPT codes in the vicinity of 63043 and 63044 are all SI T (i.e., 63001, 63003, 63005, 63011, 63012, 63015, 63016, 63017, 63020, 63030, 63040, 63045, 63046, 63047). Only 63043 and 63044 are classified as SI C and payable just as inpatient procedures.

Both InterQual and Milliman guidelines indicate that CPT 63044 is appropriate for outpatient/ambulatory care. Milliman indicates that CPT 63043 is appropriate for ambulatory care. A recent research study even suggests that outpatient lumbar discectomy patients have a lower overall complication rate than inpatients do (see: <http://www.ncbi.nlm.nih.gov/pubmed/22814304>).

Therefore, the PRT recommends that CMS remove 63043 and 63044, add-on procedures to 63040 and 63042, from the inpatient only list to be consistent with the primary procedure and other related procedures.

Collecting Data on Services Furnished in Off-Campus Provider-Based Departments

With respect to CMS' interest in gathering data on services delivered through off-campus provider-based locations, and proposals for a collection process, the PRT seeks clarification about precisely what data CMS wishes to collect as well as how CMS intends to use the collected data. The PRT is greatly concerned why CMS is interested in unleashing this huge administrative burden upon providers.

We are uncertain about whether CMS expects modifiers to be used *solely* for services rendered in off-campus provider-based departments. It is unclear to us how CMS intends to track whether different services were provided in two *separate* provider-based off-campus locations on the same day for the same beneficiary. Does CMS intend to create modifiers that will specifically track *each* address (or location) in which services are rendered? Or, is the agency's intent to collect data on whether some services were rendered off-campus, with unmodified services representing services that were delivered on-campus?

The PRT believes that using a modifier is not the best methodology due to the operational burden and confusion it will create. Many states have different definitions of off-campus for licensing from CMS' definition, and providers may not understand how to report the modifier correctly for CMS' purposes. And, if CMS limits the modifier requirement to

specific services, it will preclude the agency from truly tracking *all* costs associated with off-campus locations.

We firmly believe that creating modifier(s) to append to off-campus services will be not be feasible from an operational perspective. Providers will have two options: either manually apply the modifiers, or setting up specific line items in their Charge Master. The labor to replicate and maintain the unique line items in the Charge Master in order to report the modifier will consume additional resources as well as increase labor costs to manage this requirement.

We also note that lab, pharmacy, and other ancillary items are assigned to specific cost centers (and not charged or billed directly from an off-campus department's cost center). Our information systems are not sophisticated enough to assign a charge line item *with* a specific modifier to identify off-campus location use as well as assigning a charge for the same line item *without* the modifier for onsite campus locations. There is no common denominator to use to program systems to identify the two different location types. These types of situations will require manual intervention to apply the modifier specifically for services provided in off-campus clinics, which will result in an enormous number of resources to operationalize.

We understand that the agency is interested in this information and seeks to collect these data. The PRT could not come to consensus on a methodology for doing so that would work for all members. Our difficulty stems from not understanding the agency's specific aim, since information about the frequency and type of services can be obtained from both professional and hospital claims. We did reach consensus on the following suggestions for CMS associated with this issue:

1. In order to capture the information about what services are being billed as off-campus provider based services, the best methodology would be to report a new place of service code specifically for off-campus provider based departments on the CMS-1500 form to capture the professional services information.

CMS could then correlate the professional services to the hospital claim for same patient and same date of service. This correlation would reflect the services and units that were provided to the same patient. While the professional claim may have only one service reported, most UB-04 claims will have multiple services reported on the technical side, since the hospital providers will have provided the services ordered by the physician in the off-campus clinic.

2. A second suggestion is to create a new bill type for off-campus site locations, if the issue of combining claims is addressed and approval from NUBC is obtained. We note that CMS would have to review, and potentially revise, the requirement to combining all services on one claim (i.e., either off-campus or on-campus).

Hospitals are the hub of new models of care and there are, inherently, more costs related to the hospital processes and services due to the range of services provided in this setting.

The PRT is concerned that the data collected will be hugely flawed and do not understand the agency's intentions for using these data once they have been collected.

Physician Certification of Inpatient Services

CMS proposes several changes to the requirements related to inpatient physician certification. The PRT wishes to express our appreciation to CMS for changing the regulations to allow documentation within the medical record to support the medical necessity of an inpatient admission without a formal certification. We are deeply supportive of this change, and believe it will have a positive impact on beneficiary health.

In addition, we request that CMS agree to accept the 20-day certification noted in 1814(a)(3) of the Act as fulfillment of the certification requirement noted in 42 CFR 482.30(c) (4) and (e) (2). We believe that CMS should also update the table in *Medicare General Information, Eligibility, and Entitlement*, Chapter 4 ("Physician Certification and Recertification of Services, Section 80"), which states that physicians must certify every 12 days.

The PRT also requests that the requirement to certify the inpatient stay based on an outlier (cost or length of stay) be eliminated. Any certification based on an outlier is difficult for all hospitals, and virtually impossible for some hospitals to implement. We do not believe it adds any value to the system.

The PRT recommends that CMS provide additional education to contractors regarding the two-midnight rule, as not all actions appear to be in concert with CMS' intent. Our MACs have expressed a concern that the guidance the contractors receive about this rule changes on a regular basis. This means that a review that has been approved in the past might not be approved in the future — and vice versa. We compliment the MACs in that they have been very open to discussion with hospitals about the reasons underlying decisions rendered during the probe and educate program.

We are concerned about those cases in which the patient does not meet the need for further observation services, and does not meet the criteria for inpatient admission either. These patients literally have nowhere to go, except to go home alone — but that is not possible based on patient safety concerns. These patients need medical services but other levels of care will not accept the transfer, because there has not been a three-day qualifying stay. When these patients are discharged, family members often report to the QIO that they should have stayed — and the QIO agrees with the family. Hospitals follow CMS requirements for issuing an ABN/HINN that the stay no longer meets inpatient criteria.

The two-midnight rule was originally intended to address concerns about some Medicare beneficiaries having long outpatient stays, and to improve the integrity of inpatient admissions to acute care hospitals, critical access hospitals, long term care hospitals and inpatient psychiatric facilities. The PRT seeks clarification from CMS about whether

these goals have been met, and if the outcomes align with the agency's intentions and/or expectations.

We respectfully request CMS to provide CY 2014 data (to be presented at the CY 2015 meeting) regarding the two-midnight rule and the demonstration program regarding waiving a three-day qualifying stay for SNF admission. We seek to understand what the data show regarding the number of readmissions from a SNF back to the hospital, based on the demonstration project. Have they increased, decreased, or stayed the same?

Finally, the PRT requests that the Final Rule contain clarification from CMS that an admission order is no longer required as part of the physician certification.

APC Restructuring

The PRT appreciates the effort on CMS' part to stabilize variation in APC payment rates. We have concerns with several of the proposed changes, however, which we detail below.

1. EEG Studies: CPT codes 95965 and 95966

95965: Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (e.g., epileptic cerebral cortex localization)

95966: Magnetoencephalography (MEG), recording and analysis; for evoked magnetic fields, single modality (e.g., sensory, motor, language, or visual cortex localization)

CMS proposes to delete APC 0065 (IORT, MRgFUS, and MEG) and to reassign the services to APC 0446 (Level IV Nerve and Muscle Services). CPT codes 95965 and 95966 would be moved to this new APC.

The PRT is concerned, since CPT 95966 had an increase and decrease in the geometric mean cost within a three year period. We ask CMS to postpone this change pending further data analysis.

2. We have not identified any narrative, clinical homogeneity, or geometric mean cost reference to explain the APC movement for the following CPT codes. We ask CMS to continue further claims data analysis prior to any changes.

Cardiology Remote Device Checks: CPT code 93226 (External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report). Moving CPT 93226 from APC 0097 to 0099.

GI Esophageal Wireless capsule: CPT code 91111 (Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report.) Moving CPT 91111 in APC 0419 to 0142.

Special Treatment Procedure: CPT code 77470 (Special treatment procedure, e.g., total body irradiation, hemibody radiation, per oral or endocavitary irradiation.) CPT code 77470, Special Treatment Procedure from APC 0299 to 0412.

3. *Nerve Conduction Studies: CPT code 95908; 3-4 studies*

CPT code 95908 is a new CPT code for 2014; we do not think there are enough data to justify the change in APC from 0216 to 0218. We ask that CMS allow another year of data for review in the claims data analysis before the agency moves CPT 95908 into a different APC.

Hospital Outpatient Quality Reporting Program Updates

The PRT appreciates that CMS' goal is to align the clinical quality measure requirements of various quality reporting programs. Consistency among these measures will reduce the operational burden needed to comply with multiple sets of quality measures.

Despite supporting the overall goal, however, the PRT continues to have a broad concern that applies to many of these measures. Specifically, we note that follow-up for several of these procedures usually occurs *outside the hospital outpatient department*. Many patients are seen for follow-up in their physician's office. This means that hospitals have *no way* of assessing the patient's outcomes, as indicated by these quality measures. The PRT believes it is unfair use these measures to penalize *hospitals* for negative outcomes and inadequate results, when those facilities are not consistently responsible for conducting follow-up.

The PRT once again endorses the concept of further selection of measures for the Hospital OQR. We recommend that *all* quality measures selected should have an easily identifiable correlation to clinical outcomes and to the patient's experience of care.

Removal of Quality Measures From the Hospital OQR Program Measures Set

The PRT supports the new proposed criteria for removal of "topped out" measures. If meaningful improvements in performance are no longer being achieved, hospitals should not continue to focus their efforts on reporting the measure. Instead, they should use their resources to gather meaningful data.

We also support the removal of "topped out" measures OP4 (Aspirin at Arrival), OP6 (Timing of Antibiotic Prophylaxis) and OP7 (Prophylactic Antibiotic Selection for Surgical Patients). These practices have become a standard of clinical care.

OP-27: Influenza Vaccination Coverage Among Healthcare Personnel

The PRT supports the proposal to report data to NHSN by the enrolled facility's CMS Certification Number (CNN), rather than separately for inpatient and outpatient

departments. A single count across all settings is a more reasonable approach to gathering these data and will reduce unnecessary duplication of effort.

Delayed Data Collection for OP-29 and OP-30

The PRT supports the delay in Data Collection for the two colonoscopy measures (OP-29: Endoscopy/Polyp Surveillance - Appropriate follow up Interval for Normal Colonoscopy in Average Risk Patients; OP-30: Endoscopy/Polyp Surveillance - Colonoscopy Intervals for Patients with a History of Adenomatous Polyps).

We recommend, in fact, that these measures *not* be implemented at all. We agree that a large number of colonoscopies are being performed, but believe that this is a result of the Medicare beneficiary population's age, rather than overutilization.

In addition, we note that these indicators are a measure of *physician* quality rather than of the facility where the procedure is performed. Since these data are already collected through PQRS #320, the PRT objects to these being used as hospital indicators.

OP-31: Cataracts – Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery

The PRT supports the delay in data collection for this measure and recommends that CMS remove the measure from future data collection. The PRT objects to this as a hospital measure.

We agree with CMS that it is operationally difficult for hospitals to collect and report the data. Hospital facilities do not always see these patients at 90 days post-surgery. Follow-up is likely to occur in a different setting than the hospital outpatient department. As such, we believe this is an inappropriate quality measure for our facilities, as it does not reflect the quality of care the hospitals may provide.

With respect to the proposal to *voluntarily* report data on OP-31, the lack of hospitals' access to the data needed to report whether the patient's visual acuity has improved will lead to a complete non-participation by hospitals. While we agree with CMS that "*HOPDs should be a partner in care with physicians using their facility,*" physicians do not routinely provide information from a patient's office record after the hospital visit. The patient's legal hospital medical record typically ends at discharge. Pre-operative office visit information is often supplied for inclusion in a medical record, but post-operative visit information from a private physician's office would not be supplied.

Proposed New Quality Measures for the CY 2017 Payment Determination and Subsequent Years

CMS proposes one new claims-based measure: OP-32: Facility 7 Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy: All cause, unplanned hospital visits (admissions, observation stays and ER visits) within 7 days of an OP Colonoscopy.

We recognize that CMS seeks to “*reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care.*” We support that goal, but note that, for any colonoscopy performed outside of the hospital outpatient department, hospitals have *no* control at all over preparation, the procedure itself, or for follow-up care. Adding this quality measure would force hospitals to ask each and every patient who presents to the Emergency Department whether they have had a colonoscopy in the last week. Such an inquiry is bound to be confusing, annoying, and irrelevant to the vast majority of ED patients.

We are additionally concerned by CMS’ proposal to exclude (a) patients with concomitant high-risk upper GI endoscopy, (b) patients with history of IBD or diverticulitis in the year preceding colonoscopy, and (c) patients who lack continuous enrollment in MC FFS Part A and B in the one month after procedure. As above, how are facilities to assess this patient history? We note that there is no code for this. We seek clarification from CMS about how facilities will know, having asked the patient if he or she has had a recent colonoscopy, whether there was also a high-risk upper GI endoscopy? The logistical nightmare and risks to patient satisfaction are both significant.

The PRT does *not* support the use of this measure of hospital outpatient department quality. We believe it is unfair to penalize *hospitals* for negative outcomes and other inadequate results from a procedure that occurred elsewhere. Finally, we note that this measure is not NQF endorsed.

Possible Hospital OQR Program Measures and Topics for Future Consideration Electronic Clinical Quality Measures

The PRT supports CMS’ belief that all patients, their families, and their health care providers should have consistent and timely access to health information in a standardized format that can be securely exchanged between those involved in the patient’s care.

We support the use of health information exchanges. We note that many hospitals are already participating in other programs (such as Stage 2 of the Medicare and Medicaid EHR Incentive Program “Meaningful Use”) that promote electronic availability of records for continuity of patient care. While we appreciate and support the submission of data electronically to reduce administrative burden, the PRT remains concerned about open access to hospital medical records.

The PRT does not support CMS having direct access to a facility EHR for data abstraction. As an alternative, the PRT recommends that CMS allow hospitals to participate in the development of standards for specific data submission. Additionally, the PRT recommends CMS allow sufficient time for hospitals to create a one-way interface for electronic submission to CMS of the selective data. It is the recommendation of the PRT, that any quality measure selected should have a very clear measure that correlates to clinical outcome.

Partial Hospitalization Program Measures

The PRT understands that CMS seeks comments on three Partial Hospitalization Program (PHP) measures for consideration as Hospital OQR measures: 1) 30-Day Readmissions, 2) Group Therapy, and 3) No Individual Therapy. The PRT believes that using these measures would be a duplication of effort, since all three are currently measured and reported in the Program for Evaluating Payment Patterns Electronic Report (PEPPER).

CMS also seeks input on other possible quality measures for partial hospitalization services for inclusion in future years. The PRT makes the following recommendations on the proposed quality indicators and discharge requirements for PHP:

- CMS should require PHP programs to identify a specific appointment within 14 days of discharge from the PHP; this discharge continuing care information must be provided directly to the follow-up provider
- CMS should establish Quality Service Criteria for use in judging performance, including criteria relating to at least the following aspects of care:
 - Access: The number of program days of scheduled operation from the time of a request for services to the first scheduled day of service.
 - Treatment intensity: The percentage of scheduled attendance consistent with a minimum attendance average of 4 days per calendar week over an episode of care.
 - Discharge planning: The percentage of patients with a scheduled follow-up appointment within 14 days of discharge (as needed).
 - Continuity of care: The percentage of post-discharge continuity of care plans provided to providers at the next level of care upon discharge.

Behavioral Health Measures

CMS seeks recommendations on appropriate behavioral health measures, stating: *Because of the prevalence of depression and alcohol abuse and their impact on the Medicare population, we believe that we should consider measures in these and other behavioral health areas for use in future Hospital OQR Program payment determination years.*”

The PRT appreciates and understands CMS’ concerns about beneficiary wellness, and we recommend that the agency work with NQF to develop appropriate measures. CMS already has a wealth of behavioral health quality measures, such as those used in nursing home and home health care settings. We assume that the agency staff have reviewed these quality measures but, if not, encourage them to do so to assess their applicability in the OPSS setting.

In addition, several professional organizations active in this area may be able to provide additional guidance on appropriate quality measures.

We caution that any measures used must be claims-based and not generated by chart abstracts. Providers must be able to implement the quality measure without undue administrative burden. We will be happy to provide additional feedback when specific measures have been proposed.

Proposed Medical Record Documentation Requests for Validation and Validation Score Calculation for the CY 2017 Payment Determination and Subsequent Years

The PRT strongly supports the proposal to give hospitals the option to either submit paper copies of patient charts or to securely transmit electronic versions of medical information for validation. The prevalence of electronic medical records lends itself well to electronic submission of records. Hospitals have gained significant experience with delivery of electronic records on CD, DVD or flash drive (as allowed by RACs and requested by attorneys and other third-party requesters). Many have invested in technology to copy and submit in electronic formats.

We appreciate the development of the Secure File Transfer Portal that allows providers to transfer files containing PHI in a manner that does not compromise privacy of protected health information.

Conclusion

The PRT understands and supports the need to report quality indicators for Medicare outpatient beneficiaries. We believe, however, that the all quality indicators required by CMS must be very specific and must relate to the patient's *current* outpatient visit.

We also ask, once again, for CMS to provide information about how reporting a specific measure affects the measurement of hospital quality and how facilities can ensure that the data are captured efficiently.

Partial Hospitalization Program

The PRT has concerns about the fluctuation in APC payments for Partial Hospitalization Program (PHP) services. In addition, we note that physicians are billing inpatient codes rather than PHP codes, based on the CPT guidelines. This situation changed in 2013 with the introduction of new psychotherapy codes. When a physician does not report the psychotherapy codes, it makes it impossible for facilities to report the facility fee. We believe that the change in physician reporting may have altered, in turn, what facilities reported — which would have reduced the number of facility fees reported, and skewed the APC data downward.

We recommend that CMS conduct an analysis of the frequency and type of CPT codes that have been submitted for PHP payment over the last three years. We believe the agency will see differences in the volume of codes and in the type of services reported based on unclear instruction issued by CMS and the American Medical Association (AMA). In the CPT section on PHP, the AMA suggests that physicians bill an initial or

subsequent inpatient evaluation and management code for PHP services, rather than the outpatient psychiatric CPT codes. Since some physicians do not report the outpatient psychiatric CPT codes, facilities may lack a “trigger” to bill the facility fee for the PHP service.

This unclear billing instruction could have reduced the number of facility charges reported, and skewed the APC data downward. In addition, it may have caused hospitals to under-report the services provided per day, which are used in the calculation of APC I or APC II for PHP. We believe CMS will find observable differences in the volume of codes due to the changes made for physicians reporting these services based on CPT guidance. We expect CMS to observe a downward trend over the last few years based on this change.

While we do not have the ability to run these data and validate our assumption, we believe it is a reasonable explanation for the situation. We request that CMS report, in the Final Rule, the number of instances that physicians reported an inpatient E/M code in Place of Service 52; this would encourage providers to create an alternative process to appropriately generate outpatient PHP charges.

In addition, we request that CMS instruct contractors to provide additional education regarding the outpatient facility charge for PHP encounters.

Other Concerns

OPPS Advisory Panel

The PRT appreciates the work and acknowledges the importance of the OPSS Advisory Panel. According to the Federal Register published on April 5, 2014, only two of the available five open membership positions were filled.

We would like to understand why CMS did not fill all of the available positions. We would also like to encourage CMS to accept more hospital revenue cycle representatives to join the panel as these individuals have the coding, billing, finance, and hospital operations knowledge that would be very useful as the Panel continues to deliberate changes to the OPSS. We are interested in learning whether CMS intends to fill the remaining positions by the panel’s 2015 Summer Meeting?

We hope that the positions will be filled with Hospital Revenue Cycle representatives in order to fulfill the charter language “in a manner that ensures a balanced membership.”

ESRD and HOPPS Providers

From 1996 until 2012, patients with acute kidney injuries (AKI) were allowed to be dialyzed at ESRD facilities “under arrangement.” CMS instructed hospitals to bill for the care under the hospital’s NPI at the composite rate and to reimburse the ESRD facility under arrangement. The PRT is aware that ESRD facilities may not bill for acute dialysis.

In 2012, CMS banned AKI patients from receiving dialysis at ESRD facilities. CMS clarified that AKI patients may *only* receive services at a hospital that has a non-certified ESRD dialysis facility. Although hospitals use the claims processing instructions outlined in the Claims Processing Manual (Chapter 4, Section 200.2), which allows hospitals to bill CPT code 90935 on a hospital outpatient claim (TOB 131), contractors deny these claims. The contractors' denial is based on the belief that the treatment was provided in an acute care setting rather than the hospital's outpatient dialysis unit.

Per a PRT member's discussion with CMS staff, there is a concern that CPT code 90935 pays considerably more than the composite rate that is paid to ESRD facilities. The PRT requests that CMS consider allowing hospitals that own hospital-based ESRD facilities to bill for acute dialysis provided directly by the hospital or provided under arrangement by the ESRD facility at the composite or similar rate, as was allowed prior to 2012.

The PRT also requests CMS to provide the data that reflect the number of claims submitted by hospital providers. There is a specific CPT code for hospitals to bill (CPT code 90935). It is our understanding that contractors have been instructed *not* to reimburse providers in the circumstances noted above. The PRT requests that CMS report the data for how many claims were submitted and how many claims were reimbursed when a non-ESRD diagnosis is on the claim.

Drug Screening Codes

The PRT is aware that the AMA will delete the 80100-80104 series of drug screening CPT codes for CY 2015 and replace them with significantly more descriptive drug screening codes; it will also change the frequency nomenclature from "per test" to "per date of service."

Over the course of CYs 2010 and 2011, CMS created and refined several G-codes (currently G0431 and G0434) for use in place of the 80100-80104 series of drug screening CPTs. The rationale for the HCPCS creation was CMS' desire to avoid unnecessary or excessive use of the CPT codes by limiting drug testing reporting to once per date of service.

The use of the G-codes has been a continuous source of confusion and burden for the provider community due to the fact that other payers do not recognize either the codes or the "per patient encounter" concept. The coding instructions from Medicare are difficult to operationalize and providers must typically manually manipulate their claims processing systems for Medicare patients in order to report the HCPCS code and correct unit of one. Because the HCPCS codes do not match the CPT codes one-to-one, and the nomenclature is unclear, continued coding consternation persists in the provider community.

For instance, CMS replaced 80101 (immunoassay method) with G0431 to include multiple classes tested rather than each single class, and set the maximum units at one per

encounter. In various MLN and other published interpretive guidance documents, CMS has defined the G0431 code using a variety of terms, including “more complex testing methods, high complexity, multi-channel analyzer, instrumented lab setting, immunoassay, repeat use design” and G0434 using terms including “very simple test methods, dipstick, cups, cassettes, cards to interpret visually or with assistance of a scanner or moderately complex device outside instrumented lab setting, other than chromatographic.”

Common instrumented lab settings utilize a multi-channel analyzer, a more complex testing method (not cups, dipsticks, etc.) that can be used repeatedly to process these tests. The PRT is uncertain if CMS intended to utilize CLIA category (i.e., high, moderate) complexity in the HCPCS definitions, or if the agency created its own “definition” of test method based on the descriptors.

It is not uncommon for test equipment to have a CLIA designation of moderate complexity rather than high complexity and meet the remaining criteria for the CMS HCPCS code definition of high complexity (multi-channel, instrumented lab setting, immunoassay, etc.). In addition, these tests do not meet the G0434 definition as generated by CMS (non-instrumented, very simple, cups, dipsticks, etc.). The inclusion of high *and* moderate complexity in the HCPCS definitions appears to have confounded the coding assignment, since the original codes did not include this distinction.

Finally, we believe CMS failed to consider the discrepancy between CLIA category and its definition of high-complexity method. This calls into question how urine drug screens should be coded when the method meets the definition for high complexity (G0431) yet the FDA rates the equipment used as moderate complexity. In this example, none of the other moderate complexity definition is met with the test method used.

The PRT urges CMS to eliminate the confusion and to adopt the new AMA CPT coding methodology for drug screening for CY 2015 in its entirety, and discontinue the use of G-codes. If it does not do so, at a minimum, CMS should clarify whether or not G0431 should be used for (CLIA-designated) moderate complexity tests performed on multi-channel equipment in an instrumented lab setting.

Attachment A: 2014 Provider Roundtable Members

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